REMARKS

Claims 72-94 and 96-97 are being examined in this application.

Support for the term of emulsifier in claim 72 is found in the specification as originally filed in, *inter alia*, the paragraphs [0001]; [0058], [0060] and [0062].

By amendment of claim 72 the rejection under 35 USC § 112 is now rendered moot.

According to the Office Action claims 94 and 95 are rejected under 35 USC § 112, first paragraph, because the specification while being enabling for treating a health disorder does not reasonably provide enablement for preventing or prophylactic treatment of a health disorder. This is respectfully traversed.

Claim 94 is a method of use claim which claims a method for prevention of the health disorder by administration of a biologically active in the form of a drug delivery system of claim 72. One skilled in the art as well as lay people know that there are health disorders, diseases and medical conditions that can be prevented by prophylactic treatment. Administration of drugs or other biologically active molecules to prevent health disorders, diseases or medical conditions is known. For example, it is known to administer antibacterial drugs prophylactically to prevent secondary bacterial infections when a patient is afflicted with a viral infection. Vaccines are prophylactic compositions aimed at protecting an individual to prevent occurrence of a disease. A vaccine is administered to a patient not for treatment but for formation of antibodies which will guard against any future antigens causing the disease.

It is clear to one skilled in the art that any prophylactic treatment using a drug delivery system of the invention would be directed against the health disorder to which that particular class of drugs is indicated. For example one would not use an anti-microbial agent in a drug delivery system of the claimed invention for prevention or prophylaxis of a cancer patient. One will have to use an antineoplastic drug in the

drug delivery system of claim 72 to provide a prophylactic effect to the cancer patient. The health disorder as claimed refers to specific health disorders for which drugs are known in the prior art, but are formulated using a drug delivery system of the claimed invention.

The scope of claims 94 and 95 as included in the previous response are enabled and all rights to claim this aspect of the invention in this application or any continuation or divisional application is preserved.

Therefore, it is respectfully requested that the rejection be withdrawn.

Claims 91,92, 94 and 95 are objected to under 37 CFR 1.75 (c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only.

Claims 91, 92, 94 and 95 are not multiple dependent claims. Claims 91 and 94 depend from claim 82 only. Claim 92 and 95 depend from claim 83 only.

According to the Office Action claims 72-75, 82, 84, 91, 93, 94, 96 and 97 are rejected under 35 U.S.C. 102 (b) as being anticipated by Anastasiu et. al (RO 79581). This is respectfully traversed.

The abstract is quoted below for the Examiner's reference:

RO 79581 A UPAB: 19930925

In conditioning oily inactivated vaccine against Newcastle's disease, the vaccine contains 70% oily phase. The proportion of emulsifier in the oily phase is 3 pts. Antigen concentration is 10%. 20% collagen is used for the remainder of aqueous phase. Inactivation with aqueous HCHO solution takes place subsequently at reduced temperature, e.g. 4-8 deg. C.

This abstract suggests to an ordinary person that this delivery composition / system comprises 70% oily phase and 30% aqueous phase. Collagen is used to form the remaining 10-30% of the bulk aqueous phase. Thus the delivery composition / system comprises both an oily and aqueous phase.

The drug delivery system of the present invention is entirely different and does not comprise any aqueous phase (emphasis added). The present inventive delivery system has a continuous phase and discontinuous phase and forms microparticles in-situ, only when the components of the drug delivery system come in contact with an aqueous fluid (see claim 73) and paragraph [00018] of the specification. The invention comprises an oily phase devoid of an aqueous phase. Anastasiu uses collagen as a polymer in the aqueous phase as seen from the basic abstract. Anastasiu's composition is a ready to use delivery system comprising both oily and aqueous phases.

A printed publication will anticipate a claim under § 102(b) only " if each and every [claim] limitation is found either expressly or inherently in a single prior art reference". (Celeritas Techs. Ltd. V. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998)). In other words, a printed publication must include all "limitations" of a claim (Richardson v. Suzuki Motor Co., 868 F.2d 1226,1236 (Fed. Cir. 1989)). Merely identifying within the prior art all of the various parts of the claimed subject matter is not anticipation. Instead "there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention" (Scripps Clinic & Research Found. V. Genentech Inc., 927 F.2d 1565,1576 (Fed. Cir. 1991)).

If a claim limitation is not found expressly in a prior art reference, the court may inquire as to whether the missing descriptive matter is necessarily inherent in the thing described in the reference (Cont'l Can Co. USA., v. Monsanto Co., 948 F.2d 1264,1268-69 (Fed. Cir. 1991)). Although extrinsic evidence may be referred

to "to explain the disclosure of a reference", the Federal Circuit has stated that the role of extrinsic evidence is to educate the decision maker and not to fill gaps in the reference (Scripps, 927 F.2d at 1576, see also Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707,716 (Fed. Cir. 1984)).

Inherent anticipation "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient". (In re Oelrich, 666 F.2d 578,581 (CCPA 1981) (quoting Hansgirg v. Kemmer, 102 F.2d 212,214 (CCPA 1939). To be inherent, an undisclosed feature must necessarily and inevitably flow from practice of what is disclosed. Id.

The question of whether a printed publication includes all of the claim limitations, expressly or inherently, is a question of fact. Minn.Mining & Mfg. Co. v. Chemque, Inc. 303 F.3d 1294,1301 (Fed. Cir. 2002); Schreiber, 128 F.3d at 1477.

The drug delivery system of the present invention is devoid of one element of Anastasiu-namely the aqueous phase and thus each and every element of Anastasiu is not included in the claims. The drug composition or system of Anastasiu would not form microparticles in-situ or on coming in contact with an aqueous fluid and hence is totally different from the present invention. As each and every limitation of claims 72-75, 82, 84, 91, 93, 94, 96 and 97 are not disclosed in Anastasiu, these claims are not anticipated by the reference.

It is respectfully requested that the rejection be withdrawn.

According to the Office Action, claims 72-77, 79-83 and 91-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaleta et al. (US 5,618,522). This is respectfully traversed.

Kaleta discloses oil-in-water emulsions wherein both phases contain emulsifiers. The Examiner discusses the types of emulsifiers and other components of the compositions. However, to reiterate what was discussed above, the drug delivery composition of the present invention is devoid of an aqueous phase. The microparticles which are formed are generated "in-situ" on contact of the drug delivery system of the present invention with an aqueous medium. The delivery system of the present invention is devoid of the element of an aqueous component. The Kaleta disclosure would not form microparticles on contact with an aqueous phase and as seen from claim 1 of this patent, is an oil-in-water emulsion composition for topical application. In contrast the drug delivery system of the present invention is not an oil-in-water emulsion composition and hence is completely different. Therefore, claims 72-77, 79-83 and 91-97 are not anticipated by Kaleta and it is respectfully requested that this rejection be withdrawn.

According to the Office Action, claims 72-77, 79-82, 84, 91, 96 and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Tominaga (US 5,747,049).

Tominaga discloses a method of inhibiting cutaneous aging by applying a composition of his invention to the skin. This relates to a topical composition. The Examiner in discussing the different components of the oily phase, the anti-inflammatory agents, the oils etc. also states that the composition of Tominaga has two phases namely the oily phase and the aqueous phase. The oil-in water composition of Tominaga would not form microparticles on contact with an aqueous medium. Again applicants reiterate that the present invention is devoid of an aqueous phase and is not an oil-in-water emulsion composition. The microparticles for drug delivery are formed only when the drug delivery system of the present invention comes in contact with an aqueous medium. The present invention is completely different from Tominaga and Tominaga does not anticipate claims 72-77, 79-82, 84, 91, 96 and 97.

Therefore, it is respectfully requested that the rejection be withdrawn.

Claims 72-77, 80, 82, 90-92, 93, 94, 96 and 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta et. al. (US 6,841,539).

Mehta et al. (US 6,841,539) discloses topical cream compositions for topical drug delivery of oligonucleotides. The Examiner describes that these compositions are in the form of emulsions including micro emulsions and creams. The contents of the aqueous phase and oily phase are disclosed in the specification of the '539 patent. See for example, col. 6, lines 4-29 and, col. 8, lines 31-36. As discussed above, the drug delivery system of this invention is devoid of an aqueous phase. In the present invention, the microparticles are formed only when the drug delivery system of the present invention comes in contact with an aqueous phase. Example 6 of Mehta describes use of homogenization to form particles of mean diameter of 1.0 μm. In the present invention the microparticles of the claimed diameter are formed as a result of the drug delivery system coming in contact with an aqueous phase. Homogenization is not involved. The present invention is not an oil-in-water emulsion composition and is completely different from the compositions disclosed in Mehta.

Therefore, it is respectfully requested that the rejection be withdrawn.

Claims 88 and 89 are rejected under 35 USC 103(a) as being unpatentable over Mehta et al. (US 6,841,539). This is respectfully traversed.

The non-obviousness requirement is set forth in 35 USC § 103(a).

Obviousness is a conclusion of law based on following factual determinations: (1) scope and content of prior art, (2) the differences between prior art and the claimed subject matter as a whole, (3) the level of skill in the art, and (4) where relevant, objective evidence of non obviousness, i.e., the secondary

considerations. (Graham v. John Deere Co., 383 U.S.1, 17 (1996); see also Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530,1535-39, 1541 (Fed. Cir. 1983)). The first three obviousness factors cited above comprise the *prima facie* case (Winner Intl Royalty Corp. v. Wang, 202 F.3d 1340,1350 (Fed. Cir. 2000).

The claimed invention must be viewed " in terms of the state of the art that existed at the time the invention was made," (Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044,1050-51 (Fed. Cir. 1988)(quoting Interconnect Planning Corp. v. Feil, 774 F.2d 1132,1138 (Fed. Cir. 1985)).

A proper obviousness analysis requires recognition of prior art, not hindsight knowledge of a patentee's success and the prior art must motivate a person skilled in the art to do what the patentee has done (Yamanouchi Pharm Co. v. Danbury Pharmacal Inc., 231 F.3d 1339,1343 (Fed. Cir. 2000)).

When prior art "teaches away" from claimed invention rather than motivating a person of ordinary skill in the art to do what patentee has done, the claimed invention is non-obvious (In re Hedges, 783 F.2d 1038,1041 (Fed. Cir. 1986); W.L.Gore & Assocs. V. Garlock, Inc., 721 F.2d 1540,1552-53 (Fed. Cir. 1983)).

The prior art must also provide a reasonable expectation of success (Boehringer Ingelheim Vetmedica, Inc. v. Schering Plough Corp., 320 F.3d 1339,1354 (Fed. Cir. 2003); (In re Dow Chem. Co., 837 F.2d 469,473 (Fed. Cir. 1988)). "Obvious to try" is not sufficient Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367,1380 (Fed. Cir. 1986).

As explained above Mehta is related to oil-in-water compositions which are in the form of creams for topical administration. The present inventive drug delivery system is devoid of the aqueous phase and microparticles are formed in-situ, when the drug delivery system comes in contact with an aqueous medium. It

would not be obvious to one skilled in the art at the time of invention to even visualize that the particles sizes as included in claims 88 and 89 would be obtained in-situ without any mechanical process such as homogenization described in Mehta. Thus the delivery system of this invention is non obvious over Mehta et al.

Therefore, it is respectfully requested that this rejection be withdrawn.

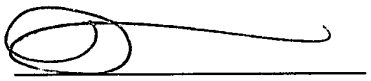
Claims 85-87 are rejected under 35 USC 103(a) as being unpatentable over Mehta et al. (US 6,841,539).

This rejection is respectfully traversed for the reasons explained above.

Mehta et al disclose a composition comprising an oily and aqueous phase. The present invention is devoid of aqueous phase. Furthermore, the present invention has the polymer in the discontinuous phase dissolved in a water soluble organic solvent and not in an aqueous phase and thus is differentiated from Mehta. Mehta uses an aqueous phase to dissolve the polymer. In the claimed drug delivery system of this application, the polymer is dissolved in an organic solvent, which is not aqueous but the polymer is miscible with the aqueous phase which it encounters when the drug delivery system is introduced into the body. The process of Mehta which is emulsification by homogenization of the oily and aqueous phases is not a part of the present invention as there is no emulsification between oily and aqueous phases. In the present invention the emulsifier is used to gel the non-polymeric phase which is discontinuous. Furthermore, the microparticles of claim 87 are formed instantaneously without any process intervention, on contact of the delivery system with the aqueous medium. Therefore, as the invention of claims 85-87 is not obvious nor expected from Mehta it is respectfully requested that the rejection be withdrawn.

Applicants submit that the current application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



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